Serial No.: 09/835,992 -5- Art Unit: 1642

Conf. No.: 6680

REMARKS

Claims 13-15, 31 and 32 were previously pending in this application. Claim 31 has been amended. New claim 62 has been added. As a result claims 13-15, 31-32 and 62 are pending for examination with claims 13 and 31 being independent claims. No new matter has been added.

Applicants would like to thank the Examiners for the courtesy extended in granting the telephonic interview of March 5, 2004. In the Interview Summary mailed March 8, 2004, the Examiner indicated that written description and enablement rejections were discussed. Applicant believes this is an incorrect statement of the issues discussed. Applicant agrees that the written description rejection was discussed, along with the indefiniteness rejection (35 U.S.C. §112, second paragraph). However, as there is no outstanding enablement rejection of the claims, no such rejection was discussed.

Objection to the Specification

The Examiner objected to the disclosure based on the priority information. As suggested by the Examiner, Applicant has amended the relevant paragraphs to include patent numbers. Reconsideration is respectfully requested.

Objections to the Claims

The Examiner objected to claim 31 based on several informalities. Applicant has amended the claim to limit it to the elected invention (use of antibodies in the claimed method) and to correct the text of the claim as suggested by the Examiner. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 13-15, 31 and 32 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses the rejection.

Conf. No.: 6680

Examiner Blanchard and Examiner Helms conducted a telephone interview on March 5, 2004 with Applicant's representatives John Van Amsterdam and Marie Jepson, and Assignee's representative Dr. Jonathan Skipper to address the issues underlying the rejection of claims 13-15, 31, and 32 under 35 U.S.C. §112. Applicants provide the following summary of the content of the telephone interview.

The interview began with a summary of the claimed invention and the related field of gastric cancer diagnostics by Dr. Jonathan Skipper. Methods set forth in the application were summarized by Dr. Skipper in the telephone interview. Dr. Skipper described the process by which the proteins that give rise to the immune response in gastric cancer were identified by Applicant using SEREX methodology. Dr. Skipper indicated that the polypeptides that Applicant identified as giving rise to an immune response in gastric cancer can be used to diagnose gastric cancer in patients. Dr. Skipper explained that the claimed methods of diagnosing gastric cancer include contacting sera obtained from a subject with sterol carrier protein-X/sterol carrier protein-2 polypeptides identified by Applicants as expressed in patients with gastric cancer. After contacting the polypeptides with the sera, one can determine whether antibodies are present in the subject's sera that recognize the polypeptide, i.e., whether the subject has mounted an immune response against the polypeptide. The presence of such antibodies in the sera is an indication of gastric cancer in that subject, either a primary tumor or a metastatic tumor that expresses the polypeptide.

Examiner Helms requested Applicants explain how the techniques used to screen patients known to have gastric cancer, as shown in the previously submitted Declaration, could be used to diagnose patients where it is not known that the patients have gastric cancer. Dr. Skipper responded stating that the patients in the study submitted in the Declaration (dated June 24, 2003, submitted July 11, 2003) were not selected, and that these results provided a demonstration of the diagnostic value of Applicant's claimed method. Applicant's representative John Van Amsterdam added that the submitted Declaration showed that normal non-cancerous patients had no sterol carrier protein-X/sterol carrier protein-2 antibodies and the technique would therefore only identify those patients with gastric cancer.

Serial No.: 09/835,992 - 7 - Art Unit: 1642

Conf. No.: 6680

Examiner Helms requested additional information regarding the open reading frames of the identified nucleic acid sequences, SEQ ID NOs:19-22. The open reading frames for these nucleic acids are provided with this amendment (see Exhibits A-1, A-2, A-3 and A-4, translated sequences). Applicant's representative John Van Amsterdam stated that the sequences found using the SEREX method had to have open reading frames which were the same as the SCP-X protein in gastric cancer in order to be identified using this method. Dr. Skipper added that once the nucleic acid sequences are discovered they are run through a database for matches and that the identified sequences matched nucleic acid molecules encoding the sterol carrier protein-X.

Examiner Helms also requested the open reading frames because according to the Examiner, there was nothing in the claims stating the function of the SCP-X protein or how to identify which region the nucleic acid sequence matched. Dr. Skipper responded stating that it is only required that the nucleic acid encode an immunogenic protein and from knowing the nucleic acid sequence it would be routine for one of ordinary skill in the art to determine the corresponding region of SCP-X.

Examiner Blanchard asked how one would differentiate from other antibodies present in the mix. Dr. Skipper responded by providing some of the method details for a Western blot or ELISA assay for detecting an antibody of interest and stated that these were standard methods well known in the art that would distinguish between a variety of antibodies by reducing non-specific binding of antibodies.

Based on the specification as filed and on the information and arguments presented in the telephonic interview of March 5, 2004, which are summarized above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 13-15, 31, and 32 under 35 U.S.C. § 112, first paragraph.

Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 31 and 32 under 35 U.S.C. §112, second paragraph, as indefinite. Applicant has amended the claims to address the first two rejections, and respectfully traverses the third rejection.

The Examiner stated three indefiniteness rejections, as follows.

Serial No.: 09/835,992 - 8 - Art Unit: 1642

Conf. No.: 6680

(1) Claims 31 and 32 were rejected for the recitation of "parameter" in claim 31. Applicant has amended claim 31 to specify that antibodies are assayed in the claimed method.

Accordingly, Applicant believes the rejection is moot.

- (2) Claims 31 and 32 were rejected for the recitation in claim 31 of "said peptide of said protein," for which there was alleged not to be antecedent basis. Applicant has amended claim 31 to remove recitations of peptides in the claimed method. Accordingly, Applicant believes this rejection is most also.
- (3) Claims 31 and 32 were rejected for the recitation of "following progress of a therapeutic regimen" in claim 31. Applicant respectfully requests reconsideration of the rejection based on the information provided in the telephonic interview.

As established, the presence of antibodies to SCP-X/SCP-2 are an indicator of gastric cancer in a patient. Patients have gastric cancer may be treated by surgery to remove the cancer, and/or radiation therapy or chemotherapy to kill the tumor, thereby removing the source of the SCP-X/SCP-2 protein. The reemergence at a later time of antibodies to SCP-X/SCP-2 would be an indication of regrowth of the tumor or of a metastatic tumor expressing SCP-X/SCP-2. Therefore, Applicant asserts that the progress of a therapeutic regime can be followed using the claimed method in which the presence or level of antibodies is determined at separate times.

In view of the foregoing claim amendments and arguments, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 31 and 32 under 35 U.S.C. §112, second paragraph.

Serial No.: 09/835,992 - 9 - Art Unit: 1642

Conf. No.: 6680

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted, Yuichi Obata, Applicant

Rv.

John R. Van Amsterdam, Reg. No. 40,212

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2211

Telephone: (617) 720-3500

Docket No. L0461.70112US00

Date: March 11, 2004

x03/11/04x

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Exhibit A-1 (SEQ ID NO: 19)

Translate Tool - Results of translation

Please select one of the following frames:

5'3' Frame 1
RQKKLF Stop FSIKHSSQSIILS YISLNFKK Stop H Stop Y Stop KN Stop EKR
Stop Met QIIKLT Stop KRKIITKD Stop ERYKLK Stop D YNLKTASESKLYCSI
XLNDGVL Stop LIH Stop FFKKETHVKNIFILKISLCSSSDHISFILIWEXN
TVSDS Met KCKIFRFLISLILXTIEKLIND Met KCTTLITGQLLALCFLLS
SPKGKLLN Stop IF SRIILKYTL Stop AKQKLFCLHSSLGFYCS Stop FYSET
QFYPRP Stop LPY Stop LCXAQLFANS

5'3' Frame 2
ARKSYFNFLLNILLKALFYPISHStopILRNNISIRKTRKKDKCRStopLN
LHEKGKLStopQRTENVINStopNEIIIStopKLHLKANFIVQLXLMet Met VF
YDStopYTDFSRRKPMetLKIFLFStopKStopACVQALIIFLLFStopFGXKIL
FLIAStopNAKFLDFStopSHStopFStopXLLRNStopLMetTStopSAQHStopLLA
SCWHCVSYLVLPRENSStopIESSAEStopSLNILCKQNKSFFVYIVLWD
FTVPNFILKLNFTPDHNYHINFVXHSCLPI

5'3' Frame 3
PEK VILIF Y Stop TFF SKHYFILYLTEF Stop EITLVLEKLGKKINADN Stop
TY Met KKENYNKGLRTL Stop IE Met RL Stop FEN CI Stop KQTLLFNYX Stop
Stop W C F Met TNTLIF QEGNP C Stop KYFYFKNKP V FKL Stop SYFFYFDLG
XKYCF Stop Stop HE Met QNF Stop I FNLTNFXNY Stop EID Stop Stop HE V HNTN
YWPAVGIVFLT Stop FSQGKTLKLNLQQNNP Stop I Y FVSKTKAFLFT
Stop FFGILLFLILF Stop NSILPQTIITILTLXCTVVCQF

3'5' Frame 1
Stop I G K Q L C X T K L I W Stop L W S G V K L S F R I K L G T V K S Q R T Met Stop T K K L L F C L Q S I F K D Y S A E D S I Stop E F S L G R T K Stop E T Q C Q Q L A S N Stop C C A L H V I N Q F L N S X Stop N Stop Stop D Stop K S K N F A F H A I R N S I X F P N Q N K R N Met I R A Stop T Q A Y F Stop N K N I F N Met G F L L E K S V Y Stop S Stop N T I I K X N Stop T I K F A F R C S F Q I I I S F Q F I T F S V L C Y N F P F S C K F N Y L H L S F F L V F L I L Met L F L K I Q Stop D I G Stop N N A L R R Met F N R K L K Stop L F L A

3'5' Frame 2
ELANNCAXQS Stop YGNYGLG Stop N Stop V SE Stop N Stop EQ Stop N PKELCK QKSFCFAYKVYLRIILLKIQFKSFPLGELSKKHNANS WPVISVVHF Met SLINFSIVXKISEIKNLKILHF Met LSETVFXSQIKIKEIStop SELEHR LIFKIKIFLT WVSFLKNQCISHKTPSLXIIEQ Stop SLLSDAVFKL Stop SH FNL Stop RSQSFVIIFLFHVSLIICIYLFS Stop FF Stop Y Stop CYFLKFSEI Stop DKI Met L Stop EECLIEN Stop NNFF W

3'5' Frame 3

NWQTTVXNKVNMet VIMet VWGKIEFQNKIRNSKIPKNYVNKKAFVLLTKYIStop GLFCStop RFNLRVFPWENStop VRNTMet PTAGQStop LVLCTS CHStop SISQStop XLKLVRLKIStop KFCISCYQKQYFXPKSKStop KKYDQSLNTGLFLKStop KYFStop HGFPS Stop KISVLVIKHHHStop X Stop LNNKVCFQMet QFSNYNLISIYNVLSPLLStop FSFF Met Stop V Stop LSAFIFFPSFSNTNVIS Stop NSVRYRIK Stop CFEKNVStop Stop KIKITFSG

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		Exhibit A-2 (SEC) ID NO: 20)	

Translate Tool - Results of translation

Please select one of the following frames:

5'3' Frame 1 ILIFY Stop TFFSKHYFILYLTEF Stop XITLVLEKLGKKXNADN Stop TY Met K K E N Y N K G L R T L Stop I E Met R L Stop F E N C I Stop K Q T L L F N Y S Stop Stop W C F Met T N T L I F Q Stop G N P C Stop K Y F Y F K N K P V F K L Stop S Y F F Y F D L G R KYCF Stop Stop HE Met QNF Stop IFNLXNFKNY Stop EID Stop Stop HEVHNTN YWPAVGIVFLT Stop FSQGKLLN Stop IFSXITLNILC Stop PNKTFLFT Stop

FFGFYCS Stop FYSETPFFPRP Stop LPYLTLLCTVV

5'3' Frame 2

F Stop F S I K H S S Q S I I L S Y I S L N F X K Stop H Stop Y Stop K N Stop E K R X Met Q I I K LT Stop KRKIITKD Stop ERYKLK Stop DYNLKTASESKLYCSIILNDGVL Stop LĪH Stop FFNKETH VKNIFILKĪSLCSSSDHISFILI WEENT VSDS Met K C K I F R F L I X L I L R T I E K L I N D Met K C T T L I T G Q L L A L C F L L S S P K E N S Stop TESSXE Stop P Stop I Y F V S Q T K L F C L H S S L D F T V P N F I L K L H F S P D H N YPIStopLCYAQL

5'3' Frame 3

FNFLLNILLKALFYPISH Stop ILXNNISIRKTRKKDXCR Stop LNLHEKG K L Stop Q R T E N V I N Stop N E I I I Stop K L H L K A N F I V Q L F L Met Met V F Y D Stop YTDFSIRKPMetLKIFLFStop K Stop A C V Q A L I I F L L F Stop F G K K I L F L I A Stop NAKFLDF Stop SX Stop F Stop ELLRN Stop L Met T Stop SAQH Stop LLASCW HCVSYLVLPRKTLKLNLQXNNLKYTLLAKQNFFVYIVLWILLFLILF Stop NSIFPQTIITLFNFV Met HSC

3'5' Frame 1

NNCA Stop QS Stop I G Stop L WS GEKWS FRIKLGTVKS KELCKQKS FV WLT KYIStop GYXAEDS V Stop EFSLGELS KKHNANS WPVIS VVHF Met SLINF SIVLKIXEIKNLKILHF Met LSETVFSSQIKIKEI Stop SELEHRLIFKIKIF LTWVSLLKNQCISHKTPSLRIIEQStop SLLSDAVFKLStop SHFNLStop R SQSFVIIFLFHVSLIICIXLFS Stop FF Stop Y Stop CYXLKFSEI Stop DKI Met L Stop E E C L I E N Stop N

3'5' Frame 2

TTVHNKVKStopGNYGLGKNGVSEStopNStopEQStopNPKNYVNKKVLF G Stop Q S I F K V I X L K I Q F K S F P W E N Stop V R N T Met P T A G Q Stop L V L C T S C H Stop S I S Q Stop F L K L X R L K I Stop K F C I S C Y Q K Q Y F L P K S K Stop K K Y D Q S LNTGLFLK Stop KYF Stop HGFPY Stop KIS VLVIKHHH Stop E Stop LNNKVC FQMetQFSNYNLISIYNVLSPLLStopFSFFMetStopVStopLSAXIFFPSFSN TNVIX Stop NSVRYRIK Stop CFEKNV Stop Stop KIK

3'5' Frame 3

QLCITKLNRVIMet VWGKMet EFQNKIRNSKIQRTMet Stop TKKFCLANK VYLRLFXStop RFSLRVFLGRTKStop ETQCQQLASNStop CCALHVINQF LNSSStop NStop XDStop KSKNFAFHAIRNSIFFPNQNKRNMet IRAStop TQ AYFStop NKNIFNMet GFLIEKSVYStop SStop NTIIKNNStop TIKFAFRCSF QIIISFQFITFSVLCYNFPFSCKFNYLHXSFFLVFLILMet LFXKIQStop D IGStop NNALRR Met FNRKLK

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. , . ,		Exhibit A=3 (SEO	TD NO: 21)	

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Please select one of the following frames:

5'3' Frame 1
LTQLLLRCLG Met LEKNIWKN Met EQKLNTLQKLDGKIINIQLITRIPS
SK Met NTV Stop Met K Stop WHLKKFLIF Stop LSYNVVPLQ Met VLQQQFWP
VKHLYRS Met ACNPKLWKF WHKK Stop Stop LICQARLKKKALLKWLAL
I Stop VKKLQENA Met RNLA Stop HQ Met ILT Stop Stop NFTIAFLPTNSLL Met
KHWDSVQKDKVQRWLIEEIIH Met EESGS Stop ILVVD Stop FQRDTH Stop
ALQVLLSVQNSAGS Stop EGKPEKRQSSWCKGGSXA Stop FXHWRNCG
CNTLQDGVFPEAASSF Stop NSSKLKXVPTKLCKXXV Stop XKIXF Stop R
XIEKEXXKREXGTICERKXRXEFLPFKGKXWPWGVKXGHPGVVG

5'3' Frame 2
SPSCSSDVWVCWKRTYGKIWNKNStopTLCKNWMetEKSStopTFSStop
StopPVFPVPRStopIQFRStopSDGIStopRSFStopFFDYLTMetLSHFRWCCS
SNFGQStopSICTEVWPAIQSCGNFGTRNDDStopFAKLVStopRKKHY
StopNGWLStopYEStopRSCKKMetLStopEIWPDTKStopYStopRNRTSRLLF
YQRTPYLStopSTGTLSRRTRCNAGStopStopRRStopYIWRKVGHKSStop
WWTDFKGTPTRRYRSCSVCRTLLAAERGSRKRGKVPGAKVALXHN
LXIGGTVVVTLYKMetGFSRKPPVPFRTHQNStopSXFQPSSASXXFXX
KSXFKXGLRRKXXRGXGEQFVKEKXXGNFCPSRGXNGPGGStopKXA
TLGWWD

5'3' Frame 3
HPVAPQMet FGYAGKEHMet EKYGTKIEHFAKIGWKNHKHSVNNPYS
QFQDEYSLDEVMet ASKEVFDFLTILQCCPTSDGAAAAILASEAFVQK
YGLQSKAVEILAQEMet Met TDLPSSFEEKSIIKMet VGFDMet SKEAAR
KCYEKSGLTPNDIDVIELHDCFSTNELLTYEALGLCPEGQGATLVDR
GDNTYGGKWVINPSGGLISKGHPLGATGLAQCAELCWQLRGEAGK
EAKFLVQRWLCXIIXALEELWLStopHSTRWGFPGSRQFLLELIKIEA
XSNQALQXXGLXXNXVLKXDStopEGNXKEGXGNNLStopKKNXXGIF
ALQGEXMet ALGGKRXPPWGGG

3'5' Frame 1
IPPPQGGXLLPPRAIXSPStopRAKIPXXFFFHKLFPXPSXXFPSQSXFK
XRFXXKXXTCRAWLEXASILMetSSKRNWRLPGKPHLVECYNHSSSN
XStopIMetXQSHLCTRNFASFPASPLSCQQSSAHStopARPVAPSGCPFEI
SPPLGFMetTHFPPYVLSPLSTSVAPCPSGQSPSASStopVRSSLVEKQS
StopSSITSISFGVRPDFSStopHFLAASLLISKPTILIMetLFSSNELGKSVI
ISCAKISTALDCRPYFCTNASLAKIAAAAPSEVGQHCKIVKKSKTSL
DAITSSKLYSSWNWEYGLLTECLStopFFHPIFAKCSIFVPYFSICSFPA
YPNIStopGATGStop

3'5' Frame 2
SHHPRVAXFYPPGPXFPLEGQKFXPXFSFTNCSXFPLXXFLLNXPLK
XDFXLNXXLAELGWNXLQFStop Stop VLKGTGGFRENPIL Stop SVTTTV
PPMet XKLCXRATFAPGTLPLFRLPLSAASRVLHTEQDLStop RLVGVP
LKSVHHStop DLStop PTFLHMet YYLLYQPALHLVLLDRVPVLHKStop G
VRWStop KSNREVLLRQYHLVSGQISHSIFLQLLYSYQSQPFStop Stop C
FFLQTSLANQSSFLVPKFPQLWIAGHTSVQMet LHWPKLLLQHHLKW
DNIVRStop SKNQKLLStop Met PSLHLNCIHLGTGNTGYStop LNVYDFSI
QFLQSVQFLFHIFPYVLFQHTQTSEEQLGE

PTTPGWXSFTPQGHXFPLKGKNSXXIFLSQIVPXSLFXVSFSIXLStop NXIXXStopTXXLQSLVGXGFNFDEFStopKELAASGKTPSCRVLQPQFL QCXNYXAEPPLHQELCLFSGFPSQLPAEFCTLSKTCSAStopWVSLStop NQSTTRIYDPLSSICIISSINQRCTLSFWTESQCFISKEFVGRKAIVKF YYVNIIWCQARFLIAFSCSFFTHIKANHFNNAFFFKRAWQISHHFLC QNFHSFGLQAILLYKCFTGQNCCCSTIStopSGTTLStopDSQKIKNFFR CHHFIStopTVFILELGIRVINStopMetFMetIFPSNFCKVFNFCSIFFHMetF

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Exhibit A-4 (SEQ ID NO: 22)

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Please select one of the following frames:

5'3' Frame 2
AKKXYXNFLLXXLXKXLFXPXXXXXXXXXXXXXXKFXKKNNXKXLT
XLEXGNXYQXXEXXXIXXXIIXXXRXXKPXXMet VQLSXXRXFXX
Stop XXDFPIXXPXLKXFXF Stop K Stop PXXQPXIXFLXFGLGKKXXFXI
XXXAXFLNF Stop PPXF Stop XLXKXXLXT Stop I ANPXXXPXVGXXFLTX
SPQGXXLXXXSXKITLXYPW Stop PXQNLFXLXXPWDLTGPQFXXEP
XFPXNHXYHFTLVRXSXLXXRKXVXFPXXFPPXLGKNGXGPPLKKQ
PSPXFGPXXXPV Stop I R T I K

5'3' Frame 3
PKKXIXISY Stop XSSXXHYXTLXXXXFXKXPXXLKNXGKKIXANX
Stop PXLKXEIXTXGXKXX Stop XEXKLXXEXGXXNQXXWSNYPXXGX
XXTNXXIFQXGXXX Stop XXFXFKNNXXSNPXSXSFXLDWGKKXXSX
YXEXQXF Stop IFNPPXFKXYXKXDXXLELPTLXXGHXWXXXSLLXP
PKEXP Stop XEXXPK Stop PLXILGNQXKTFXVYXXLGI Stop RVPNXIXN
PXFPXTIXTILPW Stop GXXVCXXAXQXXSXGXFPRXLGKTGXVPPLK
NNLPXPLAQXXFPSKSEQ Stop K

3'5' Frame 1
LFIVRIStop TGXXPGPKXGEGCFLRGGXIPFFPRXGGKXXGXXTXLR
XCKXLXLTKVKW Stop XWXGGKXGXGXNWGPVKSQGXXKXKRFXF
GYQGXLRVILXEXXXKXFPWGX Stop VRXXXPXGGXXXXGLAIQVXN
XXFXXF Stop X Stop GG Stop KFKXFXXXXGXXNXIFFPNPNXRNXIXGWX
XGYF Stop NXXXFXXXFXIGKXGX Stop XXXXLXXDNWTXKXGFXXXF
XXIIXXXIXXXXVXWXKFXFSXKVXYLXLFFFXGFLXXKVXXXXX
XXIGXNNXLXRXXNRKXK Stop XFLA

3'5' Frame 2
FLLFGFRREXXLGQRXGKVVFStop GGDXSRFSQXSGEXAXGXXLXCXANXXALPRStop NGXYGXGEXWVXDXIGDPLNPKXXVNXKGFXLVTKDXStop GLFWXXFXLRXFLGGXKStop GXXXPXVAXXStop GWQFKXXIXFXIXFKXRGVKNLKXLXFXVXGXXFFSPIQXKGXStop XGVGX

XVIFKXKXXLXXXSXLENXXISXXXPXXRIIGPXXLVXXAXFXX Stop FXFXLXXFXSXGXNFXFQXRLXICXYFFSXVFStopXXRXFXKXXXX Stop GXIMet XXGGXLIGNXNXFFW

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